

DOCKET NO.: CARP-0057



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of: **Adair et al.**

Serial No.: **08/846,658**

Group No.: **1642**

Filed: **May 1, 1997**

Examiner: **M. Davis**

For: **Humanised Antibodies**

RC 11642/17  
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TECHNICAL CENTER 1600/2900  
#37  
106-21

I, **Doreen Yatko Trujillo**, Registration No. 35,719 certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

On September 7, 2001  
Doreen Yatko Trujillo  
Doreen Yatko Trujillo, Reg. No. 35,719

Assistant Commissioner for Patents  
Washington DC 20231

Sir:

**REQUEST FOR RECONSIDERATION AND REQUEST FOR CONTINUED  
EXAMINATION (RCE) TRANSMITTAL LETTER**

Transmitted herewith for filing in the above-identified patent application is:

- ☒ A Request for Reconsideration responsive to the Office Action Dated **September 8, 2000**. A Notice of Appeal was filed March 8, 2001, received in the U.S. Patent Office on March 12, 2001.
- ☒ Other: **Copy of Chothia and Lesk, J. Mol. Biol., 196:901-917, 1987 (pages 901 and 904) reference, copy of Interlocutory Decision in Opposition Proceedings (Articles 102(3) and 106(3) EPC) and Request for Continued Examination.**
- ☐ Applicant(s) has previously claimed small entity status under 37 CFR §1.27.

## FEE CALCULATION

☐ No Additional Fee is Due.

				SMALL ENTITY		NOT SMALL ENTITY	
	REMAINING AFTER AMENDMENT	HIGHEST PAID FOR	EXTRA	RATE	FEE	RATE	FEE
TOTAL CLAIMS	08	08 (20 MINIMUM)		\$9 EACH	\$	\$18 EACH	\$
INDEP. CLAIMS	02	02 (3 MINIMUM)		\$40 EACH	\$	\$80 EACH	\$
FIRST PRESENTATION OF MULTIPLE DEPENDENT				\$135	\$	\$270	\$
<input type="checkbox"/> ONE MONTH EXTENSION OF TIME				\$55	\$	\$110	\$
<input type="checkbox"/> TWO MONTH EXTENSION OF TIME				\$195	\$	\$390	\$
<input type="checkbox"/> THREE MONTH EXTENSION OF TIME				\$445	\$	\$890	\$
<input checked="" type="checkbox"/> FOUR MONTH EXTENSION OF TIME				\$695	\$	\$1390	\$1,390
<input type="checkbox"/> FIVE MONTH EXTENSION OF TIME				\$945	\$	\$1890	\$
<input type="checkbox"/> LESS ANY EXTENSION FEE ALREADY PAID				minus	(\$ )	minus	(\$ )
<input type="checkbox"/> TERMINAL DISCLAIMER				\$55	\$	\$110	\$
<input checked="" type="checkbox"/> OTHER FEE OR SURCHARGE AS FOLLOWS: Request for Continued Examination Fee							\$710
TOTAL FEE DUE							\$2,100

☒ A Check is enclosed in the amount of \$2,100.00.

☒ Petition is hereby made under 37 C.F.R. 1.136(a) to extend the time for filing of a Brief

concerning the Notice of Appeal dated March 8, 2001, received in the U.S. Patent Office on **March 12, 2001** to and through **September 12, 2001** comprising an extension of the shortened statutory period of **four month(s)**.

- ☒ The Commissioner is hereby requested to grant an extension of time for the appropriate length of time, should one be necessary, in connection with this filing or any future filing submitted to the U.S. Patent and Trademark Office in the above-identified application during the pendency of this application. The Commissioner is further authorized to charge any fees related to any such extension of time to deposit account 23-3050. This sheet is provided in duplicate.
- ☒ The Commissioner is authorized to charge payment of the following fees and to refund any overpayment associated with this communication or during the pendency of this application to deposit account 23-3050. This sheet is provided in duplicate.
- ☐ The Foregoing Amount Due for Filing this Paper.
- ☒ Any additional filing fees required, including fees for the presentation of extra claims under 37 C.F.R. 1.16.
- ☒ Any additional patent application processing fees under 37 C.F.R. 1.17 or 1.20(d).

**SHOULD ANY DEFICIENCIES APPEAR** with respect to this application, including deficiencies in payment of fees, missing parts of the application or otherwise, the United States Patent and Trademark Office is respectfully requested to promptly notify the undersigned.

Date: *September 7, 2001*

*Doreen Yatk Trujillo*  
**Doreen Yatk Trujillo**  
Registration No. **35,719**

WOODCOCK WASHBURN KURTZ  
MACKIEWICZ & NORRIS LLP  
One Liberty Place - 46th Floor  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439

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POCKET NO.: CARP-0057

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re patent application of: **Adair et al.**

Serial No.: **08/846,658**

Group No.: **1642**

Filed: **May 1, 1997**

Examiner: **M. Davis**

For: **Humanised Antibodies**

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On September 7, 2001  
Doreen Yatko Trujillo  
Doreen Yatko Trujillo, Reg. No. 35,719

Assistant Commissioner for Patents  
Washington DC 20231

Sir:

**REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL**

This is a Request for Continued Examination (RCE) under 37 C.F.R. §1.114 of the above-identified application.

1. **Submission required under 37 C.F.R. §1.114**

☐ Previously submitted

☐ Consider the amendment(s)/reply under 37 C.F.R. §1.116 previously filed on @@ (Any unentered amendment(s) referred to above will be entered).

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on @@.

☐ Other: @@.

**DOCKET NO.: CARP-0057**

**PATENT**

☒ **Enclosed**

☒ **Amendment/Reply**

☐ Affidavit(s)/Declaration(s)

☐ Information Disclosure Statement (IDS)

☐ Other:

**2. Miscellaneous**

☐ Suspension of action on the above-identified application is requested under 37 C.F.R. §1.103(c) for a period of @@ months. (Period of suspension shall not exceed three (3) months; Fee under 37 C.F.R. §1.17(i) required)

## FEE CALCULATION:

				SMALL ENTITY		NOT SMALL ENTITY	
UTILITY APPLICATIONS BASE FEE				\$355.00	\$	\$710.00	<b>\$710.00</b>
	REMAINING AFTER AMENDMENT	HIGHEST PAID FOR	EXTRA				
TOTAL CLAIMS	<b>08</b>	<b>08</b> (20 MINIMUM)		\$9 EACH	\$	\$18 EACH	\$
INDEP. CLAIMS	<b>02</b>	<b>02</b> (3 MINIMUM)		\$40 EACH	\$	\$80 EACH	\$
FIRST PRESENTATION OF MULTIPLE DEPENDENT				\$135	\$	\$270	\$
<input type="checkbox"/> ONE MONTH EXTENSION OF TIME				\$55	\$	\$110	\$
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<input checked="" type="checkbox"/> <b>FOUR MONTH EXTENSION OF TIME</b>				\$695	\$	\$1390	<b>\$1,390</b>
<input type="checkbox"/> LESS ANY EXTENSION FEE ALREADY PAID				minus	(\$ )	minus	(\$ )
<input type="checkbox"/> FEE FOR SUSPENSION OF ACTION				\$130	\$	\$130	\$
TOTAL FEE DUE							<b>\$2,100</b>



A check in the amount of **\$2,100.00** is enclosed.



Petition is hereby made under 37 C.F.R. 1.136(a) to extend the time for response to the Office Action of September 8, 2000. A Notice of Appeal was filed on March 8, 2001 and received in the U.S. Patent Office on **March 12, 2001** to and through **September 12, 2001** comprising an extension of the shortened statutory period of **four month(s)**.



The Commissioner is hereby requested to grant an extension of time for the appropriate length of time, should one be necessary, in connection with this filing or any future filing submitted to the U.S. Patent and Trademark Office

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PATENT

in the above-identified application during the pendency of this application. The Commissioner is further authorized to charge any fees related to any such extension of time to deposit account 23-3050. This sheet is provided in duplicate.



Any additional patent application processing fees under 37 C.F.R. §§1.136 and 1.17.

**SHOULD ANY DEFICIENCIES APPEAR** with respect to this application, including deficiencies in payment of fees, missing parts of the application or otherwise, the United States Patent and Trademark Office is respectfully requested to promptly notify the undersigned.

Date:

*September 7, 2001*

*Doreen Yatko Trujillo*  
**Doreen Yatko Trujillo**  
Registration No. 35,719

WOODCOCK WASHBURN KURTZ  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re patent application of: **Adair et al.**

Serial No.: **08/846,658**

Group No.: **1642**

Filed: **May 1, 1997**

Examiner: **M. Davis**

For: **Humanised Antibodies**

TECH CENTER 1600/2300

SEP 18 2001

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On September 7, 2001  
Doreen Yatko Trujillo  
Doreen Yatko Trujillo, Reg. No. 35,719

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

### REQUEST FOR RECONSIDERATION

Pursuant to 37 C.F.R. § 1.114, Applicants request reconsideration and withdrawal of the sole remaining rejection in this application. A Final Rejection was issued September 8, 2000. A Notice of Appeal was filed March 8, 2001. Advisory Actions were issued February 13, 2001 and July 31, 2001. A petition for a four-month extension of time, and the appropriate fee, accompany this request.

Preliminarily, Applicants note that an Attachment for Form PTO-948 was included with the later July 31, 2001 Advisory Action stating that drawing corrections are required within the time period set in the Office Communication. The Office Communication was an Advisory Action following a Notice of Appeal; no time period was set. Nonetheless, Applicants are forwarding corrected drawings.



The rejection of claims 24-31 under 35 U.S.C. § 102(e) in view of U.S. Pat. No. 5,585,089 (the "Queen patent") was maintained. Applicants respectfully traverse this rejection.

The Queen patent claims priority to four earlier applications, two of which are continuations-in-part of earlier applications. For the Queen patent to be entitled to the earliest priority dates as a reference under 35 U.S.C. § 102(e), however, there must be support for the claims *as allowed* in those priority applications. (See MPEP 2136.03, p. 2100-85, citing *In re Wertheim*, 209 USPQ 554 (CCPA 1981).) Applicants have maintained that several of the limitations recited in the claims as allowed in the Queen patent do not find support in at least the two earliest Queen priority applications – i.e., Queen priority Application Serial No. 07/290,975, filed December 28, 1988 ("Queen '975") and Queen priority Application Serial No. 08/310,252, filed February 13, 1989 ("Queen '252"). A chart delineating those limitations for which Applicants submit there is no support in Queen '975 and Queen '252 was attached as Appendix A to the response filed May 24, 2000, incorporated herein. If the claim limitations do not find support in those earlier applications, then the Queen patent is not effective as a reference under 35 U.S.C. § 102(e) as of those filing dates. Thus, the effective filing date of the Queen patent cannot be earlier than September 28, 1990, the next priority date. As set forth in previous responses, discussion incorporated herein, Applicants are entitled to their GB priority date of December 21, 1989. Accordingly, the Queen patent is not an appropriate reference under 35 U.S.C. § 102(e), and this rejection should be withdrawn.

One of the limitations for which Applicants have maintained there is no support in Queen '975 and Queen '252 is the recitation "outside the Kabat and Chothia CDRs." This limitation is significant because it was required for the Queen patent to be allowed. A review of the file history of the Queen patent reveals that this limitation was added very late in prosecution; it was not present in the claims as originally filed in Queen '975 nor in Queen '252. Indeed, the claims as originally filed referred merely to "CDRs."

As emphasized in the Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶1, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, January 5, 2001, p. 1099-1111, for a claim to be entitled to an earlier priority date, each claim

limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. *Id.*, at p. 1107. When an explicit limitation is not present in the original disclosure whose benefit is sought, it must be shown that a person of ordinary skill at the time the application was filed would have understood that the description **requires** that limitation. *Id.*, pat p. 1111, n. 63, citing *Hyatt V. Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 11331 (Fed. Cir. 1998) (emphasis added). Applicants maintain that this limitation was not expressly, implicitly, nor inherently supported in Queen '975 and Queen '252.

In the Final Rejection, the Examiner argued that the limitation "outside the Kabat and Chothia CDRs" is taught, for example, on page 9, lines 1-5 of Queen '975 and page 13, lines 1-8 of Queen '252. The passages cited by the Examiner, however, do not support the Examiner's position. As set forth in previous responses, the passage cited in Queen '252 does not even refer to CDRs.

The passage on page 9, lines 1-5, of Queen '975, is the only passage in either specification that has the words "Chothia" and "CDR" in the same sentence. But even that sentence does not explicitly refer to Chothia CDRs. Rather, the sentence refers to hypervariable regions, which it alleges are also called CDRs, and cites to two references: Kabat et al. and Chothia et al. This passage does not provide express support for the limitation in question. The remainders of the Queen '975 specification and the Queen '252 specification make it clear that CDRs are as defined by Kabat. Thus, there is no implicit support, nor can it be argued that one of ordinary skill in the art would have understood that the description **requires** the limitation.

In the Advisory Action, dated July 31, 2001, the Examiner argued

Since Queen et al in the specification [sic] of 07/290975 incorporate by reference the definition of CDR's by Chothia et al, in addition to the CDR's as defined by Kabat, one of ordinary skill in the art would have recognized that CDR's as taught by Queen et al would include also CDR's as defined by Chothia et al, besides CDR's as defined by Kabat et al, regardless of whether the rest of the specification discloses as examples Kabat's CDR's.

This statement is erroneous. Chothia et al. does not define CDRs; Chothia et al. describes six hypervariable loops which it carefully distinguishes from the Kabat CDRs. Indeed, on page 904, Chothia et al. (copy enclosed) states the following:

[The] limits [of the six loops] are somewhat different from those of the complementarity-determining regions defined by Kabat *et al.* (1983) on the basis of sequence variability . . .

Thus, when Chothia et al. refers to CDRs, it is referring to the Kabat CDRs. Accordingly, contrary to the allegation in the Advisory Action dated July 31, 2001, Queen '975 could not incorporate a definition of Chothia CDRs by reference to Chothia et al., and one of skill in the art could not have recognized that the CDRs as taught by Queen '975 include CDRs as defined by Chothia et al. Nor is this the appropriate standard. One of skill in the art would have to understand that CDRs as taught by the Queen patent require the inclusion of Chothia CDRs.

While understanding that the Examiner is not bound by the decisions of another patent office, Applicants enclose a copy of the "Interlocutory decision in Opposition proceedings (Articles 102(3) and 106(3) EPC)" ("Decision"), in which the Opposition Division concluded that

There is no convincing evidence for an alternative or refined definition of *Kabat et al.* CDRs by *Chothia et al.*: the latter authors simply establish the concept of the "hypervariable loop" by determining the **residues controlling the 3-dimensional conformation** as opposed to *Kabat's* definition of a CDR strictly relying on **residues determining the sequence variability**. **To this end, Chothia accepted the CDR definition of Kabat based on sequence hypervariability and merely compared his data to the Kabat CDR's by, of course, using the Kabat numbering system.**

(See "Decision," page 23, emphasis in original.)

Clearly, Chothia et al. did not define CDRs separate from the Kabat CDRs. There is no support for the recitation "outside the Kabat and Chothia CDRs" in Queen '975 or Queen '252. Applicants respectfully request that this rejection be withdrawn.

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**PATENT**

In view of the foregoing, Applicants respectfully request that the Examiner declare an interference between the present application and the Queen patent. The Examiner is requested to contact the undersigned at (215) 564-8352 if she feels a telephonic discussion will be helpful.

Respectfully submitted,

A handwritten signature in cursive script, reading "Doreen Yatko Trujillo".

Doreen Yatko Trujillo  
Registration No. 35,719

Date: September 7, 2001

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